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| 10/664,603 | 09/17/2003 | Guy A. Rouleau | GOUD:023USD1 | 3929 |

7590 12/27/2007
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| EXAMINER |
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LIU, SUE XU

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| ART UNIT | PAPER NUMBER |
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1639

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12/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/664,603

Applicant(s)

ROULEAU ET AL.

Examiner

Sue Liu

Art Unit

1639

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 December 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☒ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 14, 34, 36-41, 43 and 44.
Claim(s) withdrawn from consideration: 35 and 42.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/Jon D. Epperson/
Primary Examiner, AU 1639

Continuation Sheet

Item 3

Applicant's proposed amendments would bring new structural and/or functional limitations (such as "alpha subunit of an SCN3A", "high stringency conditions", "amino acid residue 43", etc.) into the claims (e.g. Claims 14, 34, etc.), and thus would require new searches in both prior art considerations and other issues for patentability determination. In addition, the proposed amendments to the claims would also raise the issue of new matter. For example, the recitation "amino acid residue 43 being deleted or amino acid residue 1035 being an isoleucin..." in the proposed instant claim 34 does not appear to have support in the instant disclosure as originally filed. Furthermore, the proposed claim amendments added new claims 48-51 without cancelling a corresponding number of finally rejected claims. Thus, the proposed claim amendments as filed on 12/10/07 will not be entered.

Item 11

As discussed under Item 3, the instant claims as would be amended is not entered due to consideration of new issues. In addition, the evidence (i.e. the Raymond reference) is also not entered as indicated under Item 8.

The following rejections are maintained for the reason of record.

Claim Rejections - 35 USC § 112, 1st paragraph

Written Description

Claims 14, 34, 36-41, 43 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The previous rejection is maintained for the reasons of record as set forth in the Office action.

Discussion and Answer to Argument

Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicant's traversal over the above rejection is based on the proposed amended claims that recite features that are not previously presented. However, applicant's amended claims are not entered due to requirements of new considerations, as discussed above. Thus, the above cited rejection is maintained for the reasons of record.

Scope of Enablement

Claims 14, 34, 36-41, 43 and 44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for assaying sodium channels using protein with full length SCN3A protein of SEQ ID NO:67 or the ion channel encoded by the nucleic acid of SEQ ID NO:65, as well as a method of selecting a compound using in vitro cell based ion channel assay, does not reasonably provide enablement for using any other protein fragments of SEQ ID NO:67 and/or variants of proteins encoded by SEQ ID NO:65, as well as any assay for selecting a compound that can be used for treating IGE in human or animals. The previous rejection is maintained for the reasons of record as set forth in the Office action.

Discussion and Answer to Argument

Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicant's traversal over the above rejection is based on the proposed amended claims that recite features that are not previously presented. However, applicant's amended claims are not entered due to requirements of new considerations, as discussed above. Thus, the above cited rejection is maintained for the reasons of record.

New Matter Rejection

Claims 14, 34, 36-41, 43 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The previous rejection is maintained for the reasons of record as set forth in the Office action.

Discussion and Answer to Argument

Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicant's traversal over the above rejection is based on the proposed amended claims that recite features that are not previously presented. However, applicant's amended claims are not entered due to requirements of new considerations, as discussed above. Thus, the above cited rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 112, 2nd paragraph

Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The previous rejection is maintained for the reasons of record as set forth in the Office action.

Discussion and Answer to Argument

Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicant's traversal over the above rejection is based on the proposed amended claims that recite features that are not previously presented. However, applicant's amended claims are not entered due to requirements of new considerations, as discussed above. Thus, the above cited rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 102

Clare

Claims 14, 34, 37-40, 43 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Clare et al (Conference on Molecular and Functional Diversity of Ion Channels and Receptors, New York NY May 14 – 17, 1998, published as Annals of the New York Academy of Sciences. 1999. 868: 80-83; the published article cited in IDS 10/4/06, citation # C76). The previous rejection is maintained for the reasons of record as set forth in the previous Office action.

Discussion and Answer to Argument

Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicant's traversal over the above rejection is based on the proposed amended claims that recite features that are not previously presented as well as on evidence that is not entered. However, applicant's amended claims and newly presented evidence are not entered due to requirements of new considerations, as discussed above. Thus, the above cited rejection is maintained for the reasons of record.

Applicants traverse the Clare reference and argue the Clare reference cannot be considered as a printed publication. (Reply, p.10, para 2).

The Clare reference cited was published in April 1999, which is before the earliest possible priority date for the instant application (Provisional filing date of 11/26/1999). The citation for the printed article of the Clare reference from PubMed (see attached PubMed citation print out; downloaded 11/14/06) indicates that this is a "Meeting Paper" and that the meeting was held May 14 –17, 1998, which is more than a year before the earliest possible priority date. The meeting included both oral presentations and poster presentations; the enclosed Table of Contents for the printed volume clearly lists the reference by Clare et al. as a "poster paper" (see Table of Contents for Volume 868, p. 2; cited in IDS 10/4/06, citation # C75), as opposed to an oral presentation. The reference thus qualifies as a "printed publication" within the meaning of 35 USC 102(b); see **MPEP § 2128.01(IV)**.

Applicants also traverse the inherency rationale presented in the previous mailed Office action. (Reply, pp.10-16).

As discussed in the previous Office action, a prima facie case of inherency has been made based on supporting evidence and scientific rationale. Applicants also based the traversal over the proposed claim amendments of “alpha subunit” (Reply, pp.12+). As discussed above, the proposed amendments are not entered, and thus would not overcome the outstanding rejection.

Applicants also traversed over the above rejection by relying on a newly cited reference, which is not entered. Thus, the evidence would not overcome the outstanding rejection.

Claim Rejections - 35 USC § 103

Claims 14, 34, 36-40, 41, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clare et al (Conference on Molecular and Functional Diversity of Ion Channels and Receptors, New York NY May 14 – 17, 1998, published as Annals of the New York Academy of Sciences. 1999. 868: 80-83; the published article cited in IDS 10/4/06, citation # C76), in view of Hall et al (US 5,871,940; 2/16/1999; filed 1/13/1997). This rejection is maintained for the reasons of record.

Discussion and Answer to Argument

Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Application/Control Number:
10/664,603
Art Unit: 1639

Page 8

Applicant's traversal over the above rejection is based on the proposed amended claims that recite features that are not previously presented as well as on evidence that is not entered. However, applicant's amended claims and newly presented evidence are not entered due to requirements of new considerations, as discussed above. Thus, the above cited rejection is maintained for the reasons of record.

/Jon D. Epperson/
Primary Examiner, AU 1639